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# APT Rec'd PCT/PTO 10 JAN 2006

PCT

### Attorney Docket #0288-034P/JAB

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re

U.S. Patent Application of S. Chava; S.R. Gorantla; and V.S.K. Indukuri

S.N.

10/553,821

Group Art Unit:

Unknown

Filed

October 19, 2005

Examiner

Not Yet Assigned

For

**Process For The Preparation Of Gabapentin Form-II** 

New York, NY January 

✓ , 2006

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants wish to bring the attention of the Examiner to the references set forth on the annexed Form PTO/SB/08A which may be of interest in connection with examination of the identified application. One copy of each reference identified is submitted herewith.

U.S. Patents 4,024,175 and 4,087,544 disclose Gabapentin and processes for its preparation as hydrochloride and sodium salts.

U.S. 2003/0009055, U.S. 6,465,689, U.S. 5,091,567, WO 02/44123, WO 02/34709, WO 00/01660, WO 99/14184 and EP 1174418 disclose conversion of Gabapentin hydrochloride to a corresponding free amino acid by basic ion-exchange neutralization, followed by crystallization.

U.S. 4,894,476 discloses a method for converting the hydrochloride salt of Gabapentin into a crystalline monohydrate by eluting the aqueous solution through a basic ion-exchange resin to produce a slurry to which an alcohol is added.

U.S. 5,132,451, 5,095,148, 5,091,567 and 5,068,413 disclose hydrogenation of a cyano intermediate to liberate the free amino acid.

Respectfully submitted,

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JAB/cw **ENCLS** 

REG. #28,188

# CERTIFICATE UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, on January .5, 2006

Carol L. Wood

U.S. Patent and Trageman Mice: U.S. DEFARTIMENT OF COMMERCE
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Substitute for form 1449A/PTO

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete it	Known

 Application Number
 10/553,821

 Filing Date
 10-19-05

 First Named Inventor
 S. CHAVA

Art Unit
Examiner Name

Attorney Docket Number | 0288-034P/JAB

U.S. PATENT DOCUMENTS					
Examiner	Cite No.1	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
Initials*		Number-Kind Code <sup>2 (if known)</sup>	MM-DD-YYYY	Applicant of Cited Document	
		US- 4,024,175	05-17-1977	SATZINGER et al	
		US- 4,087,544	05-02-1978	SATZINGER et al	
		US- 4,894,476	01-16-1990	BUTLER et al	
		US- 5,068,413	11-26-1991	STEINER et al	
		US- 5,091,567	02-25-1992	GEIBEL et al	
		US- 5,095,148	03-10-1992	METTLER et al	
		US- 5,132,451	07-21-1992	JENNINGSet al	
		US- 6,465,689 B1	10-15-2002	BRYANS et al	
		US- 2003/0009055 A1	01-09-2003	VELARDI et al	
		US-			

	FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant	
		Country Code <sup>3</sup> Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	T6
		WO 99/14184	A1	03-25-1999	BRYANS et al		
		EP 1174418		01-14-2004	BOSCH LLADO et al		
		WO 00/01660	A1	01-03-2000	PAI OCCI et al		
		WO 02/34709	A1	05-02-2002	CANNATA et al		
		WO 02/44123	A1	06-06-2002	FERRARI et al		$\vdash$
							+

Examiner	Date	
Signature	Considered	

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). See Kin8s Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.